

120mg tablets

fexofenadine hydrochloride

Package leaflet: Information for the user (Referred to as Allevia in the remainder of the leaflet)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after taking Allevia.

What is in this leaflet

- 1. What Allevia is and what it is used for
- 2. What you need to know before you take Allevia
- 3. How to take Allevia
- 4. Possible side effects
- 5. How to store Allevia
- 6. Contents of the pack and other information

1. What Allevia is and what it is used for

i

Allevia contains fexofenadine hydrochloride, which is a non-drowsy antihistamine.

Allevia is used in adults and adolescents over 12 years of age to relieve the symptoms of hay fever (seasonal allergic rhinitis) such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

2. What you need to know before you take Allevia



Do not take Allevia

 if you are allergic to fexofenadine or any of the other ingredients of this medicine (listed in section 6)



Warnings and precautions

Talk to your doctor or pharmacist before taking Allevia if:

- ▲ you have problems with your liver or kidneys
- ▲ you have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat

▲ you are elderly

If any of these apply to you, or if you are not sure, tell your doctor before taking Allevia.



Other medicines and Allevia

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Indigestion remedies containing aluminium and magnesium may affect the action of Allevia, by lowering the amount of medicinal product absorbed. It is recommended that you leave about 2 hours between the time that you take Allevia and your indigestion remedy.

Pregnancy and breast-feeding

Allevia should not be taken during pregnancy and whilst breast-feeding unless advised by a doctor.



Driving and using machines

Allevia is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

3. How to take Allevia

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

For adults and children aged 12 years and over

The recommended dose is one tablet (120 mg) daily. Take the tablet with water before a meal. This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours.

Allevia is not recommended for children under 12 years of age.

If you take more Allevia than you should

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Allevia

Do not take double dose to make up for a forgotten tablet. Take the next dose at the usual time.



If you have any further questions on the use of this medicine, ask your doctor or pharmacist.





4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking Allevia if you experience:

 swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patient who did not receive the drug (placebo).

Common side effects (may affect up to 1 in 10 people):

- · headache
- drowsiness
- feeling sick (nausea)
- dizziness.

Uncommon side effects (may affect up to 1 in 100 people):

• tiredness/sleepiness.

Additional side effects (frequency not known: cannot be estimated from the available data) which may occur are:

- difficulty sleeping (insomnia)
- sleeping disorders
- bad dreams
- nervousness
- · fast or irregular heart beat
- diarrhoea
- · skin rash and itching
- hives
- serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness, and difficulty breathing.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Allevia

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage condition. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Allevia contains

- The active substance is fexofenadine hydrochloride.
 Each tablet contains 120 mg of fexofenadine hydrochloride.
- The other ingredients are:
- Tablet core: microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, magnesium stearate
- Eilm coating: hypromellose, povidone K30, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400, red iron oxide (E172) and yellow iron oxide (E172).

What Allevia looks like and contents of the pack

Allevia are peach coloured, capsule shaped tablets marked with "012" on one side and a scripted "e" on the other.

Allevia is presented in blister packs, available in pack sizes of 7, 10, 15, 20, 30 tablets. Not all pack sizes are marketed.

Marketing Authorisation Holder:

Sanofi

410 Thames Valley Park Drive

Reading

Berkshire

RG6 1PT

UK

Tel: 0800 035 2525

email: uk-medicalinformation@sanofi.com

Manufacturers

Sanofi Winthrop industrie

30-36 Avenue Gustave Eiffel

37100 Tours

France

0r

Opella Healthcare International SAS

56, route de Choisy

60200 Compiègne

FRANCE

This leaflet was last revised in 07/2021



